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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,966	05/23/2006	Ezio Bombardelli	2503-1217	9265

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YOUNG & THOMPSON
209 Madison Street
Suite 500
ALEXANDRIA, VA 22314

EXAMINER	
DAVIS, DEBORAH A	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
05/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,966	BOMBARDELLI, EZIO	
	Examiner	Art Unit	
	DEBORAH A. DAVIS	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 17-21* is/are rejected.

7)☒ Claim(s) ____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response to the Office Action mailed on February 4, 2008 has been acknowledged. Currently, claims 1-22 are pending and under consideration for examination. Claims 15-16 are withdrawn from consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14, 17-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castelli et al (US 7,008,627) in view of Koch et al (US 7,166,310) and in view of Bombardelli et al (US 6,419,950) in view of Tamemoto et al (Phytochemistry, Volume 58, Issue 5, November 2001, pages 763-767).

A topical composition for the treatment of atopic dermatitis, skin allergic conditions and acne comprising (a) Ginkgo biloba terpenes; (b) floroglucinols, either pure or in a mixture thereof, extracted from elected species Hypercicum sp, and (c) Zanthoxylum bungeanum is apparently claimed.

The reference of Castelli et al beneficially teaches extracts obtained from Ginkgo biloba leaves that contain terpenes. The Ginkgo extracts have excellent anti-inflammatory activity that has been demonstrated on cutaneous cells such as

keratinocytes. The extracts are a cosmetic (i.e. atopical) for treating sensitive skin (see column 4, lines 34-67, e.g.).

The reference of Koch et al beneficially teaches topical medicaments comprising extracts of hypericum perforatum having a hyperforin content of at least 2% to 4%. According to the instant specification on page 3, hyperforin are floroglucinols. The topical medicament is useful in the treatment of acne, atopic dermatitis and other skin disorders (see abstract, and column 4, lines 37-65, e.g.).

The reference of Bombardelli et al beneficially teaches an extract of the pericarp of Zanthoxylum bungeanum for treating burns, itching and in all types of skin treatments requiring local analgesic or anti-itching action (see column 1, lines 45-67 and column 2, lines 1-10, e.g.). The extracts also contain isobutylamide content, as claimed (column 3, lines 39-45, e.g.).

The reference of Tamemoto beneficially teaches ethyl acetate extracts of air-dried fruits of Ferula Kuhistanica which includes ferutinine as an active compound that exhibited antibacterial properties (see page 8, e.g.). Tamemoto beneficially teaches that several Ferula species has been used in medicine to treat skin diseases and wounds (see page 3, e.g.).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit and to further use the combined ingredients to treat a patient in need thereof since each is well known in the art for the same purpose (e.g., treating skin conditions and antibacterial properties) and for the following reasons. It is well known that it is *prima*

facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. The adjustment of particular conventional working conditions (i.e. percentage amounts of the instant extracts) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of the evidence to the contrary.

Claims 20-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Castelli et al (US 7,008,627) in view of Koch et al (US 7,166,310) in view of Bombardelli et al (US 6,419,950) in view of Tamemoto et al, as applied to claim 1-14, 17-19 and 22

above, and further in view of Vincene M. Parrinello (US 5,578,312) and Lupulet (Pub#RO108642) are maintained for reasons of record and restated below:

The teaching of Castelli et al, in view of Koch et al, in view of Bombardelli et al (US 6,419,950) in view of Tamemoto et al has been set forth above, but does not teach lauric acid and Oenothera biennis oil as a lipophilic excipient.

The reference of Vincene M. Parrinello beneficially teaches a skin care system that includes Evening primrose (oenothera biennis) and lauric acids as active ingredients and known for their ability to enhance retention of moisture, vitamins and minerals by the skin (see column 4, lines 1-38, column 9, lines 1-11, e.g.).

The reference of Lupulet et al beneficially teaches a cosmetic day cream comprising Oenothera biennis oil as an active ingredient useful for skin having a predisposition towards acne, eczema and has emollient, moisturizing, nutritive and light protectant effects (see entire abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further include oenothera biennis oil and lauric acid taught Parrinello and Lupulet into the extracts taught by Castelli et al, Koch and Bombardelli et and Tamemoto et al above based on the beneficial teachings of their ability to retain moisture in the skin, treat acne, eczema and other benefits to the skin recited above. The adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of the evidence to the contrary.

Response to Arguments

Applicant's arguments filed February 4, 2008 have been fully considered but they are not persuasive.

Applicant argues that there is not recognition of a topical composition for treatment of atopic dermatitis, skin allergic condition or acne comprising the components of claim 1. Applicant argues that although the references are directed to skin compositions there is not recognition that each of the compositions would be suitable together. Applicant argues that there is no recognition of a composition with amount of components as recited in claim 2. Applicant argues that a particular parameter or variable must first be recognized as a result-effective variable before it can be characterized as routine or obvious. Applicant recites the case law of In re Antonie to support the position taken. Applicant concludes that the obviousness rejection is improper because the references do not provide a reason that would have prompted a person of ordinary skill in the relevant field to combine in a manner so as to obtain the claimed invention. These arguments have been fully considered but are not found to be persuasive of error.

In response, the references of Castelli, Koch, and Bombardelli are related to skin compositions that can be applied topically. The cited compositions have anti-itching, dermatitis, and acne properties therein. The compositions are suitable together because it is well known to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition. The rejection was predicated upon the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are not more than the additive effect of the ingredients. With respect to the amounts recited in claim 2, the reference of Castelli teaches Ginkgo bilboa terpenes in a preferable amount of less than 1%, Koch discloses hyperforin (i.e. floroglucinols) content of at least 2%, and Bombardelli teaches extracts of zanthoxylum bungeanum at a concentration of 0.5%. The above concentration ranges are within the cited ranges of claim 2, or so close that one of ordinary skill in the art would have a reasonable expectation of success in producing the claimed composition. Thus, the claimed ranges of claim 2 are deemed as judicious selection and routine optimization which is well within the purview of the skilled artisan. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art.

Applicant argues that the reference of Bombardelli does not apply prior art because the effective filing date of the instant application is earlier that the reference applied. This argument have been fully considered and found to be persuasive and therefore the reference of Bombardelli (US2006/0275246) is hereby withdrawn and a

new reference has been applied above that teaches ferutinine and various Ferula species.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH A. DAVIS whose telephone number is (571)272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah A. Davis
Patent Examiner
Art Unit 1655
April 2008

/Christopher R. Tate/
Primary Examiner, Art Unit 1655